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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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|-----------------|-------------|----------------------|---------------------|

09/310,740 05/13/99 BROWN S 37-49

HM12/1031

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EXAMINER

CHOI, F

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

10/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | | |
|------------------------------|-----------------|--------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/310,740 | BROWN ET AL. | |
| | Examiner | Art Unit | |
| | Frank I Choi | 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-145 and 148-190 is/are pending in the application.
- 4a) Of the above claim(s) 187-190 (except as indicated in the Office Action) is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-145 and 148-190 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 187-190 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11a</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Information Disclosure Statement

Examiner reiterates that the information disclosure statement filed 12/19/00 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed is required. It has been placed in the application file, but the information referred to therein has not been considered. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Election/Restrictions

Applicant elected composition and method claims in Paper No. 9 (3/15/01) which has been treated as an election without traverse because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement. Apparatus claims were withdrawn from consideration and subsequently cancelled by Applicant. As such, Applicant cannot now submit claims 187-190 which appear to be directed to an apparatus in that the coated substrate and intermediate product comprise a conveyor belt. As such, claims 187-190 are withdrawn from consideration, except as addressed below under 35 USC 101/112, as directed to a non-elected invention.

Art Unit: 1616

Claim Objections

Claims 37 is objected to because of the following informalities:

Independent claims should begin with an "A" not a "The". Appropriate correction is required.

Claim Rejections - 35 USC § 101/112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-98, 100-120, 122-135, 137-145, 148-154, 156-158, 160-186 are rejected under 35 U.S.C. 112, first paragraph, because the Specification, while being enabling for the specified types of substrates or coating apparatus, does not reasonably provide enablement for the broad scope of the claims herein. The specification does not enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The claims broadly claim a substrate or coating apparatus, however, it appears the limited direction is given as to the components of each. As such, in light of the above, a skilled artisan would be required to do undue experimentation in order to make and/or use the invention commensurate in scope with the claims.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Although Applicant has provided more examples of substrates, in total, it does not appear that said examples are sufficient to enable the scope of the term "substrate".

Claims 187-190 are rejection under 35 U.S.C 112, 2nd Paragraph, for claiming both an apparatus and method steps of using the apparatus or a product and apparatus in the same claim. Alternatively the claims are rejected under 35 U.S.C. 101 as the claims are directed to neither a "process, machine, manufacture, or composition of matter" but rather embraces or overlaps two or more different statutory classes of invention set forth in 35 USC 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. See MPEP 2173.05(p)(II).

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 98, 113, 114, 115, 116, 166 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schmidt (U.S. Pat. 4, 925,670) for the reasons of record set forth in the prior Office Action (3/13/01) and the further reasons below.

Schmidt was discussed in the prior Office Action and the same is incorporated herein.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e. removal of coating apparatus by manufacturer) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant argues that the method is different because the cited reference does not disclose a coating apparatus and the same is removed by the manufacture as opposed to the patient or hospital staff. However, "coating apparatus" does not appear to be defined, as such, the removable substrate in the cited reference does not appear to be excluded by the term "coating apparatus", and the claim does not appear to contain any limitation that any coating apparatus is removed by the manufacturer.

Claims 98, 100, 101, 103-109, 113-116, 154, 166 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt (U.S. Pat. 4, 925,670) for the reasons of record set forth in the prior Office Action and the further reasons below.

Schmidt was discussed in the prior Office Action and the same is incorporated herein.

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the same reasoning as above.

Claims 37, 38, 50-55, 75, 76, 88-92, 169, 171, 176-177, 179 and 184 rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams et al. (U.S. Pat. 5,699,649).

Abrams et al. teach a method of preparing multiple dosage units by applying discrete units of electrostatically charged powder to a belt which conveys said units of powder to packaging material (See entire reference, especially Figs. 1-6, Claims 1-12).

The difference between the cited reference and the invention is that the cited reference does not expressly disclose particle sizes. However, the prior art amply suggests the same as the mass of powder transferred is a function of mass to charge ratio of the charged particles (Column 3, lines 14-16). As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use various particles sizes depending on the composition of the powders, including particle sizes falling within the claimed ranges, with the expectation that the amount of drug could be adjusted as desired.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been taught by the teachings of the cited reference.

Claims 37-145, 148-186 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 92/14451 in view of Mlodozeniec et al. (U.S. Pat. 4,029,757).

WO 92/144451 teaches a method applying electrostatic powder, including layers of electrostatic powder, onto a medical substrate which is on a conveyor belt and fusing the same on to said medical substrate (Pgs. 5-9). It is taught that the invention is not restricted to any particular form of coating material but that the material should be able to maintain a charge, suitable materials include sugar alcohols, sugars, polyoxyethylenes and titanium dioxide (Pgs. 9-11).

Mlodozeniec et al. teach an automated method of making dosage units by applying electrostatic powder or by suspending the powder in water or an organic solvent and applying by electrostatic jet spray deposition on a web, including dosage units having several inactive and active layers, which can be divided in to individual dosage units (Columns 15-17, 24-28). It is

taught that glidants may be used such as colloidal silica to facilitate flow of powdered active substance through the deposition apparatus (Column 18, lines 14-15).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a method of electrostatically coating a substrate having multiple layers, where the active coat is applied in the form of liquid or particle size. However, the prior art amply suggests the same as it is known in the art to prepare layered dosage forms, apply coatings in the form of liquids and use various sized particles in the electrostatically applied compositions. Further it would have been well within the skill of and one ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that multiple drugs could be administered in a single dosage form, application of drugs having very small doses on the substrate can be facilitated by applying as a liquid and that appropriate particle size will facilitate deposition of the powder on the medicinal substrate.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

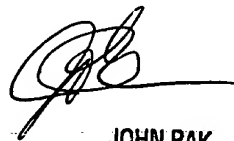
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

October 26, 2001


JOHN PAK
PRIMARY EXAMINER
GROUP 1600

